Dkt. No. 75723-ZA/JPW/GJG/PJS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: David Baltimore, et al.

Serial No.: 10/037,341 Examiner: David Guzo

Filed : January 4, 2002 Group Art Unit: 1636

Title : Nuclear Factors Associated With Transcriptional Regulation

1185 Avenue of the Americas
New York, New York 10036

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Sir:

DECLARATION OF DR. INDER VERMA

I, Dr. Inder Verma, declare as follows:

1. I am the American Cancer Society Professor of Molecular Biology at The Salk Institute, Laboratory of Genetics, La Jolla, California. A copy of my *curriculum vitae* and a list of my publications are attached hereto as **Exhibit 1.**

2. I have been retained by the applicants' counsel as a technical expert in concurrent reexamination proceeding Nos. 90/007,503 and 90/007,828, as well as in this application. I have provided testimony in reexamination proceeding Nos. 90/007,503 and 90/007,828.

I. Scope of Opinion

3. I have been provided with, and asked to review, U.S. Serial No. 10/037,341, claims 90 and 91, the Office Action dated April 19, 2007, and the various references cited within that Office

Action. I have been asked to provide an analysis of the scientific evidence relied on by the Examiner to reject certain claims of the above-identified application as expressly or inherently anticipated by these references. In particular, I have been asked to provide an analysis as to whether one of skill in the art would have understood these references to describe or disclose the elements of the above-identified application claims being rejected on the basis of these references. Where the rejection of certain claims has been made on grounds of inherency, I have been asked to analyze whether there is any basis in fact and/or technical reasoning to support a determination that elements present in these claims would necessarily result from the teachings of the cited art. For the purpose of this declaration I have understood, one skilled in this art in 1991 would have at least a doctoral degree, e.g. a Ph.D. degree, in molecular biology or a related discipline, have at least 3 years of post-doctoral training, have knowledge in cell biology, biochemistry and genetics, and be well trained in laboratory methodologies.

4. The opinions set forth in this declaration are based on my professional knowledge and expertise, as indicated in my curriculum vitae, my review of U.S. Serial No. 10/037,341, filed January 4, 2002 and the Office Action dated April 19, 2007, including the documents cited in the Office Action. For the purposes of this declaration, I have been requested to review claims 90 and 91.

II. Interpretation of the Claims

5. My interpretation of the claims is based on my understanding to how one of skill in the art would have understood the terms appearing in the claims in the context of the claims as a whole, in view of the description of the invention set forth in the patent.

6. Both of the claims under review require the act of reducing induced or activated NF-κB activity. Claims 90 and 91 recite "reducing expression in a human cell of a gene, the expression of which has been induced" by an extracellular influence that activates NF-κB. As such, both claims now under review require that NF-κB activity be induced prior to the act of administering a composition that could reduce such induced or activated NF-κB activity.

A. Inherent Anticipation rejection based on the PDR 1985, Griffith 1981 ("Griffith I") and Griffith 1984 (Griffith II)

7. I understand that Examiner has alleged that the 1985 PDR, Griffith et al. I (1982) and Griffith et al. II (1984) inherently anticipate claim 90. I understand the Examiner's position to be that the method being claimed in claim 90 is described in the 1985 PDR, Griffith et al. I, Griffith et al. II based on Holschermann et al. I respectfully disagree. I have reviewed the claims, the 1985 PDR, Griffith et al. I and II and Holschermann et al. and determined that none of these references disclose the method of the claims under review. In the sections which follow, I first present my observations of the 1985 PDR, Griffith et al. I and Griffith et al. II, and then present my observation of the non-prior art reference, Holschermann et al., which the April 19, 2007 Office Action purports explains these references.

1985 PDR

8. I have reviewed the Examiner's comments in the April 19, 2007 Office Action regarding the 1985 PDR and disagree on several points. Claim 90 recites a "method for reducing expression in a human cell of a gene, the expression of which has been induced by an external influence that activates NF-κB" (emphasis added). I understand the Examiner has alleged that the 1985 PDR teaches administration of CsA to reduce activated NF-κB activity. I find no such teaching in the 1985 PDR. The 1985 PDR provides dosage and administration instructions for the use of CsA.

Further, the 1985 PDR describes CsA as "a potent immunosuppressive agent which in animals prolongs survival of allogenic transplants involving skin, heart, kidney, pancreas, bone marrow, small intestine and lung. Sandimmune [cyclosporine] has been demonstrated to suppress some humoral immunity and to a greater extent, cell-mediated reactions such as allograft rejection, delayed hypersensitivity, experimental allergic encephalomyelitis, Freund's adjuvant arthritis and graft vs. host disease in many animal species for a variety of organs." (page 1811, third column). Importantly, the 1985 PDR discloses a specific protocol of administration: "the initial dose of Sandimmune (cyclosporine) Oral Solution should be given 4-12 hours prior to transplantation.." (emphasis added, page 1813, first column). Therefore, the 1985 PDR cannot teach a method for reducing expression in a human cell of a gene, the expression of which has been induced by an external influence that activates NF-κB as recited by claim 90.

Griffith et al. I

9. I have reviewed the Examiner's comments in the April 19, 2007 Office Action regarding Griffith et al. I and disagree on several points. Claim 90 recites a "method for reducing expression in a human cell of a gene, the expression of which has been induced by an external influence that activates NF-κB" (emphasis added). I understand the Examiner has alleged that Griffith et al. I teach administration of CsA to reduce NF-κB activity in cardiac transplantation recipients. I find no such teaching in Griffith et al. I. Griffith et al. I teach the administration of cyclosporine "orally just before operation" (page 324, second column). Even if one assumes that surgery induces NF-κB, which I am not certain that it does, administration of CsA prior to surgery is analogous to pretreatment and therefore at best prevents activation of NF-κB. Therefore, Griffith et al. I cannot teach a method for reducing expression in a human cell of a gene, the expression of which has been induced by an external influence that activates NF-κB as cited in claim 90.

Griffith II

10. I have reviewed the Examiner's comments in the April 19, 2007 Office Action regarding Griffith et al. II and disagree on several points. Claim 90 recites a "method for reducing expression in a human cell of a gene, the expression of which has been induced by an external influence that activates NF-κB" (emphasis added). I understand the Examiner has alleged that Griffith et al. II teach administration of CsA to reduce NF-κB activity in cardiac transplantation recipients. I find no such teaching in Griffith et al. II. Griffith et al. II teach the administration of cyclosporine "orally 1 to 4 hours preoperatively and continued orally, or by nasogastric tube, every 12 hours postoperatively" (page 952, second column). Even if one assumes that surgery induces NF-κB, which I am not certain that it does, administration of CsA prior to surgery is analogous to pretreatment and therefore at best prevents activation of NF-κB. Therefore, Griffith et al. II cannot teach, regardless of what Holschermann et al. disclose, a method for reducing expression in a human cell of a gene, the expression of which has been induced by an external influence that activates NF-κB as recited by claims 89 and 90.

Holschermann

11. The Examiner cited Holschermann et al. Circulation (1997) 96(12):4232-4238 to purportedly explain what occurred in each of Griffith et al. I, Griffith et al. II and upon use of CsA as taught in the 1985 PDR. However, I do not understand how Holschermann et al. can explain what necessarily occurred in any of the three prior art references cited by the Examiner. There are critical points that differ between Holschermann et al. and the prior art references. There is no evidence that NF-κB had been activated in patients prior to the administration of CsA. As I discussed in paragraph 10 above, even if surgery were to induce NF-κB, and I am not certain that

it does, the administration of CsA prior to surgery as is taught in the prior art is analogous to pretreatment and therefore at best prevents activation of NF-κB, but does not reduce induced or activated NF-κB activity as required by the claims under review.

12. Further, the protocols differ greatly between the prior art references and Holschermann et al. The protocol used by Holschermann et al. deviates greatly from the protocols outlined by the 1985 PDR, Griffith et al. I and Griffith et al. II. Patients in the prior art studies did not receive the same drug cocktail as those in Holschermann et al. and therefore it is unclear what effect, if any, CsA had on the patients. One skilled in the art would expect a cocktail of different active drugs, as described, to result in the different patient outcomes. It is unreasonable to conclude that the results observed using one cocktail of active drugs in Holschermann et al. could possibly explain what previously happened when a different cocktail of active drugs was used in the prior art.

13. Further, the timing of administration of the drug cocktails differs greatly between the prior art and Holschermann et al. Holschermann et al. do not begin CsA treatment until 3 to 4 days after surgery, a highly relevant departure from the studies described in the prior art. Therefore Holschermann et al. cannot be used to explain what occurred in the prior art.

14. Moreover, as someone of skill in the art, I do not understand the experiments described in Holschermann et al. to demonstrate that the administration of CsA reduces induced or activated NF-κB. Holschermann et al. discloses a protocol wherein "PBMCs and monocytes/macrophages were prepared from blood samples drawn from cardiac transplant recipients before and after daily CsA administration" (page 4234, first column). Holschermann et al. go on to disclose that "measurement of the corresponding CsA plasma concentration in each blood sample revealed an increase of CsA blood levels from 233 ng/mL...in the sample before daily CsA administration" (page 4234, second column) which indicates that CsA was always present in the blood.

15. Further, I have critically examined Figures 3 and 4 of Holschermann et al. which the Examiner has pointed to in alleged confirmation of the ability of CsA to reduce the levels of a protein, tissue factor (TF) which is purported to be regulated by NF-κB. I respectfully disagree with the interpretation of the results set forth in the April 19, 2007 Office Action. First, in Figure 3 (a copy of which is attached hereto as **Exhibit 2**), the sample loaded into lane 2, which is derived from blood collected from patients prior to the daily CsA administration has no detectable level of mRNA. Further, it is only after a six hour incubation can one observe a faint TF mRNA band, as indicated in lane 3. Notably, the sample collected from a patient after CsA administration and incubated for 6 hours shows no reduction in band intensity as shown in lane 6. It is only when the sample is incubated with LPS for 6 hours, can a prominent band be observed in lane 4, indicating an increase in TF mRNA transcription. These results demonstrate that the administration of CsA prevented the induction of TF mRNA by LPS as is indicated by the faint band in lane 7. Therefore, Figure 3 of Holschermann et al. shows that CsA cannot reduce existing TF transcription, though it appears to prevent activation of TF.

16. Further, I have compared these TF mRNA transcription results with those presented in Figure 4 and I disagree with the interpretation of the data as set forth in the April 19, 2007 Office Action. First, the samples depicted in the "prior to" panel cannot correlate with a sample "prepared from blood mononuclear cells freshly isolated from transplant recipients before....CsA administration" (Figure 4, legend). If this were correct, Figure 3, lane 2, would depict the presence of TF mRNA, but it does not. The lack of activated TF mRNA, which is purported to be regulated by NF-κB, in samples obtained from patients prior to CsA administration indicates there is no activated NF-κB. The only conclusion that could correlate the results in Figure 3 to Figure 4 is that the samples obtained prior to CsA administration were incubated for 6 hours in the presence of LPS to stimulate NF-κB activity. In fact, in the legend for Table 2, such a step is

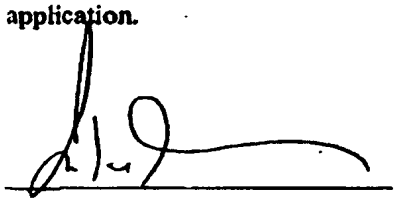
described: "Mononuclear cell were isolated from peripheral blood samples of heart transplant recipients before and 4 hours after CsA administration, respectively, and assayed for TF activity after 6 hours of incubation with LPS" (page 4235). I therefore conclude that the only interpretation that can reconcile the intense NF-κB bands observed in the "prior to" sample in Figure 4 with the results shown in Figure 3 is that the samples underwent the 6 hour incubation with LPS. Otherwise, the disconnect between the lack of TF transcription (Figure 3, lane 2) compared to intense NF-κB bands observed in the "prior to" samples in Figure 4 still exists. Since NF-κB has been shown to activate transcription of TF, the only reasonable explanation is the one provided above. Consequently, not only did Holschermann et al. not carry out the therapy protocols set forth in the prior art, but the data obtained by Holschermann et al. does not demonstrate that CsA reduced induced NF-κB activity.

Non-reproducibility of Experiments

17. I do not understand the prior art references, 1985 PDR, Griffith et al. I and Griffith et al. II to provide enough detail to enable of one skill in the art to repeat their studies and arrive at the same results. The 1985 PDR provides dosage and administration instructions for the use of cyclosporine A. I understand, as one skilled in the art, that if I practice the method described in the 1985 PDR, I will observe a number of non-responsive patients or patients who exhibit adverse reactions (see table, page 1812). Therefore, the inherent variability in patient response to CsA and lack of access to the same patients populations used in these studies render it impossible for one to repeat the studies described in the prior art and obtain the same results. The 1985 PDR notes that "several study centers have found blood monitoring of cyclosporine useful in patient management" (page 1813, second column) and Griffith et al. II emphasizes this point, noting "the principal message is the lack of correlation between the dose of cyclosporine and the whole-blood level. Monitoring of the blood level in necessary to ensure that the administered dose provides a

significant level of circulating cyclosporine" (page 954, first column). Thus, the lack of availability of the patient populations used in prior studies as well as the inherent variability in patients' responses to CsA would not enable one to practice the 1985 PDR, Griffith et al. I and Griffith et al. II studies and arrive at the same result.

18. I hereby declare that all statements made herein of my own knowledge are true and that all statements made herein on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application.



Inder Verma, Ph.D.

Oct 19/2007

Date

EXHIBIT 1
of Dr. Verma Declaration
filed October 19, 2007

Applicant: David Baltimore et al.
Serial No.: 10/037,415
Filed: January 4, 2002

INDER M. VERMA

CURRICULUM VITAE

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Date of Birth:	November 28, 1947		
Place of Birth:	Sangrur, Punjab, India		
Citizenship:	U.S. Citizen		

EDUCATION:

1971-1974	Department of Biology, Massachusetts Institute of Technology, Cambridge, MA. Postdoctoral fellow (with Dr. D. Baltimore)
1967-1971	The Weizmann Institute of Science, Rehovot, Israel, Ph.D. Biochemistry
1964-1966	Lucknow University, India M.Sc. Biochemistry

PROFESSIONAL EXPERIENCE:

6/95 - Present	Professor, Laboratory of Genetics, The Salk Institute, La Jolla, California
2/85 -6/95	Professor, Molecular Biology and Virology Laboratory, The Salk Institute
7/83 - Present	Adjunct Professor, Department of Biology, University of California, San Diego
2/83 - 1/85	Senior Member, Molecular Biology and Virology Laboratory, The Salk Institute
7/79 - 1/83	Adjunct Associate Professor, Department of Biology, University of California, San Diego
1/79 - 1/83	Associate Professor, The Salk Institute
4/74 - 1/79	Assistant Professor, The Salk Institute

HONORS AND AWARDS:

2006	Member of the American Philosophical Society
2006	AAAS Fellow
2005	Foreign Fellow, Indian National Science Academy (INSA)
2000	Fellow, American Academy of Arts and Sciences
1999	Member, Institute of Medicine of The National Academy of Sciences (USA)
1998	Associate Member, European Molecular Biology Organization (EMBO)
1997	Member, The National Academy of Science (USA)
1997	Foreign Fellow, The National Academy of Sciences, India
1997	Fellow, American Academy of Microbiology
1995	Member, The Third World Academy of Sciences
1995	Charaka Award of The Association of Indians in America

Applicants: D. Baltimore, et al.
Serial No.: 10/037,415
Filed: January 4, 2002
Exhibit 1

1993	Thrombosis Research Institute, London, Annual Award for 1993
1990	American Cancer Society Professor of Molecular Biology
1988	NIH Outstanding Investigator Award
1987	NIH Merit Award
1985	Medal for Outstanding Scientist of North American Scientists of Indian Origin
1970 - 1973	Fellow of the Jane Coffin Childs Memorial Fund for Medical Research
1967 - 1970	Reverend Solomon B. Caulker Memorial Fellowship
1964 - 1966	First in order of merit in M.Sc.

EXTRACURRICULAR SERVICES:

2006 – 2007	Chair of the Faculty and Academic Council of The Salk Institute
2001 - Present	Editorial Board of the Proceedings of the National Academy of Sciences (USA)
2001 – Present	Ceregene, Inc., member, Board of Directors and Scientific Advisory Board
2001 – Present	Xenogen, Scientific Advisory Board
2001 – Present	Jubilant Biosys, Ltd., member, Scientific Advisory Board and Board of Directors
1999 – 2004	Editor-in-Chief, Molecular Therapy (journal of the American Society for Gene Therapy)
1998 – 2001	Editoral Board of Genetic Medicine
2000 – 2001	President, American Society for Gene Therapy
1997 - Present	Agensys, Santa Monica, CA, member, Scientific Advisory Board
1997 - Present	Cell Genesys, Inc., Foster City, CA, member, Board of Directors and Chairman, Scientific Advisory Board,
1997 - 2001	Arcaris Pharmaceuticals, Salt Lake City, UT, member, Scientific Advisory Board
1995 - 1999	Editor, GENE
1995 - 1999	Member, Scientific Advisory Board of MA Bioservices, Rockville, MD
1994 - Present	Editor, Gene Expression
1998	Member, American Society for Virology
2000 - Present, 1994 – 1998, & 1989 - 1991	Member, Board of Trustees, The Salk Institute
1993 - 1999	Editor, Journal of Virology
1993 - 2001	Founder and Chairman of the Scientific Advisory Board, Signal Pharmaceuticals, Inc., San Diego, CA
1989 - 1998	Member Academic Council of The Salk Institute
1983 - Present	Coordinator of the Scientific Advisory Committee established by the Prime Minister of India for the Department of Biotechnology
1990 - 1997	Founder and Chairman of the Scientific Advisory Board, Somatix Therapy Corporation, Alameda, CA
2001 – 2002, 1996 - 1997 & 1991 - 1992	Chairman of the Faculty and Academic Council of The Salk Institute
1994 - 1995 & 1989 - 1990	Vice Chairman: Faculty and Academic Council of The Salk Institute

REVIEW COMMITTEES:

2001 – Present	Fred Hutchinson Cancer Research Center, Scientific Advisory Board
2000 – Present	Cleveland Clinic Foundation, External Advisory Board
1998 - Present	Wellcome Trust Fellowship Review Committee
1991 - Present	General Motors Sloan Selection Committee
1997 – 2006	Damon Runyon Scholar Award Committee
1997	Scientific Advisory Committee, Ben May Cancer Institute, University of Chicago
1997	Scientific Advisory Committee, Leukemia Society of America
1995	Chairman, Ad Hoc Review Committee for the Recombinant DNA Advisory Committee
1994	Quinquennial Review Committee for ICRF, London
1993	American Cancer Society Postdoctoral Fellowship Screening Committee
1992	Institute of Biomedical Sciences Scientific External Research Review, Taipei, Taiwan
1989-1993	Member, Scientific Advisory Committee of the Damon Runyon-Walter Winchell Cancer Research Fund
1986-1989	Chairman, Advisory Committee on Cell & Developmental Biology, American Cancer Society
1981-1985	Member, Virology Study Section, NIH

PUBLICATIONS:

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7. Verma IM, Meuth NL, Bromfield E, Manly K, Baltimore D 1971 A covalently-linked RNA-DNA molecule as the initial product of the NRA tumor virus DNA polymerase. Nature 233:131-134
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